UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,891	09/26/2003	Jonathan S. Stinson	10527-450001/ 02-303	9546

26161 7590 10/18/2007

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
ROE, JESSEE RANDALL	
ART UNIT	**PAPER NUMBER**
1793	
MAIL DATE	**DELIVERY MODE**
10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/672,891	STINSON, JONATHAN S.	
	Examiner	Art Unit	
	Jessee Roe	1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-12,14-21 and 41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 9-12, 14-21 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-6, 9-12, 14-21 and 41 are pending wherein claims 1, 15, 16 and 18 are amended; claims 7, 8, 13 and 22-40 are canceled; and claim 41 is new.

Status of Previous Rejections

The previous rejections of claims 1-6, 9-10, 12-15 and 19-20 under 35 U.S.C. 103(a) as being unpatentable over Steinemann et al. (US 4,040,129) in view of Draenert (US 5,047,030) is withdrawn in view of the Applicant's arguments and amendment to the claims. The previous rejection of claims 1-6, 9, 11-12 and 14-15 under 35 U.S.C. 103(a) as being unpatentable over Davidson (US 5,685,306) is withdrawn in view of the Applicant's amendment to the claims. The previous rejection of claims 16-18 under 35 U.S.C. 103(a) as being unpatentable over Steinemann et al. (US 4,040,129) in view of Draenert (US 5,047,030), and further in view of the ASM Handbook Volume 2 is withdrawn in view of the Applicant's arguments and amendment to the claims. The previous rejection of claim 21 under 35 U.S.C. 103(a) as being unpatentable over Davidson (US 5,685,306) with evidence from Wiktor (US 5,653,727) is withdrawn in view of the Applicant's amendment to the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9-12, 14-15 and 18-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not contain literal support for a molybdenum base alloy.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9-10, 12, 14, 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (US 5,643,312) in view of Steinemann et al. (US 4,040,129).

In regards to claims 1, 6, 9-10, 12, 14 and 15, Fischell et al. ('312) discloses a balloon expandable stent that would comprise a tubular body wherein the stent would

be fabricated from titanium or titanium alloy (Figure 6, col. 1, line 66 – col. 2, line 3 and col. 4, lines 5-19). However, Fischell et al. ('312) do not specify the exact composition of the titanium alloys that would be suitable for use in the stent.

Steinemann et al. ('129) discloses a corrosion resistant alloy that would be used as screws fixed in bones (col. 2, lines 27-46 and col. 4, line 51 – col. 5, line 9) comprising from 3-30 weight percent consisting of one or more of the elements from the group of niobium, tantalum, chromium, molybdenum and aluminum with the balance being titanium and/or zirconium (col. 3, lines 47-58). These alloys combine corrosion resistance, compatibility, and high strength for uses in surgery (col. 4, lines 25-29).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a balloon expandable stent comprising a tubular body, as disclosed by Fischell et al. ('312), from alloys having 3-30 weight percent consisting of one or more of the elements from the group of niobium, tantalum, chromium, molybdenum and aluminum with the balance being titanium and/or zirconium, as disclosed by Steinemann et al. ('129), in order to combine corrosion resistance, compatibility, and high strength for uses in surgery (balloon expandable stent), as disclosed by Steinemann et al. ('129) (col. 4, lines 25-29).

In regards to the limitations that the alloy have a yield strength of 45 ksi or more, a magnetic susceptibility of about +1 or less, and a mass absorption coefficient of about 1.9 cm^2/g or more of claim 1, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitations that the alloy have a UTS of about 90 ksi or more and a percent elongation of about 40 or more of claim 2, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitations that the alloy have a yield strength of about 50 ksi or greater, a percent strength to peak load of about 30 or greater, a UTS of about 90 or greater and a percent strength to fracture of about 40 or greater of claim 3, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitation that the alloy has a magnetic susceptibility of about 3.5×10^{-3} or less of claim 4, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitation that the alloy have a mass absorption coefficient of about 2.9 cm^2/g or less of claim 5, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to claim 19, Fischell et al. ('312) discloses that the stent would be 0.1 to 0.3 mm (0.0039 to 0.012 inches) thick (col. 4, lines 20-26).

Claims 1-6, 11-12, 14-15, 19 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (US 5,728,158) in view of Lenning et al. (US 3,161,503).

In regards to claims 1, 11-12 and 14-15, Lau et al. ('158) discloses a balloon

expandable stent that would comprise a generally tubular body wherein the stent would be fabricated from titanium and/or tantalum alloy where corrosion resistance would be desired (Figures 2-4, col. 7, lines 5-8 and col. 8, line 30). However, Lau et al. ('158) do not specify the exact composition of the alloys that would be suitable for use in the stent.

Lenning et al. ('503) discloses an alloy consisting essentially of from 40 to 70 weight percent tantalum, a beta stabilizer selected from the group consisting of vanadium, molybdenum, chromium, iron, and manganese from 2 to 20 weight percent, with the balance being titanium (col. 2, lines 20-26). This alloy would have improved corrosion resistance and a lower cost relative to pure tantalum (col. 2, lines 7-19).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a balloon expandable stent comprising a generally tubular body, as disclosed by Lau et al. ('158), from alloys having 40 to 70 weight percent tantalum, a beta stabilizer selected from the group consisting of vanadium, molybdenum, chromium, iron, and manganese from 2 to 20 weight percent, with the balance being titanium, as disclosed by Lenning et al ('503), in order to improve corrosion resistance, as disclosed by Lenning et al. ('503).

In regards to the limitations that the alloy have a yield strength of 45 ksi or more, a magnetic susceptibility of about +1 or less, and a mass absorption coefficient of about 1.9 cm^2/g or more of claims 1 and 41, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitations that the alloy have a UTS of about 90 ksi or more and a percent elongation of about 40 or more of claim 2, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitations that the alloy have a yield strength of about 50 ksi or greater, a percent strength to peak load of about 30 or greater, a UTS of about 90 or greater and a percent strength to fracture of about 40 or greater of claim 3, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitation that the alloy has a magnetic susceptibility of about 3.5×10^{-3} or less of claim 4, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to the limitation that the alloy have a mass absorption coefficient of about 2.9 cm^2/g or less of claim 5, the Examiner asserts that these properties would be met by the inherent material properties of an alloy with the same composition. MPEP 2112.01 I.

In regards to claim 19, Lau et al. ('158) discloses that the thickness of the tubing would be about 0.003 inches, which would be within the ranges of 0.0015 inch and about 0.0150 inch (col. 7, lines 5-15).

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (US 5,728,158) in view of Lenning et al. (US 3,161,503), and further in view of the ASM Handbook Volume 2.

In regards to claims 16, Lau et al. ('158) in view of Lenning et al. ('503) discloses a balloon expandable stent that would comprise a generally tubular body wherein the stent would be fabricated from titanium and/or tantalum alloy and corrosion resistance would be desired as shown above, but Lau et al. ('158) in view of Lenning et al. ('503) do not specify that the titanium would be commercially pure (CP) titanium.

The ASM Handbook Volume 2 discloses where commercially pure (CP) titanium would be used in applications where high strength is not a requirement and corrosion resistance is important (pg. 588, col. 3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use commercially pure (CP) titanium, as disclosed by the ASM Handbook Volume 2, as the titanium for the stent that would be fabricated from the titanium and/or tantalum alloy stent, as disclosed by Lau et al. ('158) in view of Lenning et al. ('503), in order to ensure corrosion resistance, as disclosed by the ASM Handbook Volume 2 (pg. 588, col. 3).

In regards to claims 17 and 18, Lenning et al. ('503) discloses an alloy consisting essentially of from 40 to 70 weight percent tantalum, a beta stabilizer selected from the group consisting of vanadium, molybdenum, chromium, iron, and manganese from 2 to 20 weight percent, with the balance being titanium (col. 2, lines 20-26).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (US 5,643,312) in view of Steinemann et al. (US 4,040,129), and further in view of Scott et al. (US 5,383,928).

In regards to claim 20, Fischell et al. ('312) in view of Steinemann et al. ('129)

disclose a balloon expandable stent that would comprise a tubular body wherein the stent would be fabricated from titanium or titanium alloy and the titanium alloy would contain 3-30 weight percent consisting of one or more of the elements from the group of niobium, tantalum, chromium, molybdenum and aluminum with the balance being titanium and/or zirconium. However, Fischell et al. ('312) in view of Steinemann et al. ('129) do not specify that the body would include a therapeutic agent.

Scott et al. ('928) discloses applying a sheath comprising a polymer and a drug for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen in order to allow controlled release of the drug (abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply a sheath comprising a polymer and a drug, as disclosed by Scott et al. ('928), to the balloon expandable stent, as disclosed by Fischell et al. ('312) in view of Steinemann et al. ('129), in order to allow controlled release of the drug, as disclosed by Scott et al. ('928) (abstract).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (US 5,728,158) in view of Lenning et al. (US 3,161,503), and further in view of Scott et al. (US 5,383,928).

Lau et al. ('158) in view of Lenning et al. ('503) discloses a balloon expandable stent that would comprise a generally tubular body wherein the stent would be fabricated from titanium and/or tantalum alloy consisting essentially of from 40 to 70 weight percent tantalum, a beta stabilizer selected from the group consisting of vanadium, molybdenum, chromium, iron, and manganese from 2 to 20 weight percent,

with the balance being titanium. However, Lau et al. ('158) in view of Lenning et al. ('503) do not specify that the body would include a therapeutic agent.

Scott et al. ('928) discloses applying a sheath comprising a polymer and a drug for encompassing at least a portion of a stent to locally deliver a drug to an arterial wall or lumen in order to allow controlled release of the drug (abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply a sheath comprising a polymer and a drug, as disclosed by Scott et al. ('928), to the balloon expandable stent, as disclosed by Lau et al. ('158) in view of Lenning et al. ('503), in order to allow controlled release of the drug, as disclosed by Scott et al. ('928) (abstract).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (US 5,643,312) in view of Steinemann et al. (US 4,040,129) as applied to claim 1 above, with evidence from Wiktor (US 5,653,727).

In regards to claim 21, Fischell et al. ('312) in view of Steinemann et al. ('129) discloses a balloon expandable stent that would comprise a tubular body wherein the stent would be fabricated from titanium or titanium alloy and the titanium alloy would contain 3-30 weight percent consisting of one or more of the elements from the group of niobium, tantalum, chromium, molybdenum and aluminum with the balance being titanium and/or zirconium. The stent would also include a catheter for delivery into an artery or vessel (col. 1, lines 38-52). However, Fischell et al. ('312) in view of Steinemann et al. ('129) does not specify the diameter of the balloon.

Wiktor ('727) discloses using balloon catheters that have 10 mm and 12 mm

diameters to expand a titanium stent (col. 5, lines 58-67 and col. 6, lines 28-52).

Therefore, it would be expected that the size of the expandable balloon of Fischell et al. ('312) in view of Steinemann et al. ('129) would be the same or similar to the size of the balloon of Wiktor ('727) because Fischell et al. ('312) in view of Steinemann et al. ('129) and Wiktor ('727) disclose substantially the same system; expanding a titanium alloy; and the same intended use (use in the human body).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (US 5,728,158) in view of Lenning et al. (US 3,161,503) as applied to claim 1 above, with evidence from Wiktor (US 5,653,727).

In regards to claim 21, Lau et al. ('158) in view of Lenning et al. ('503) discloses a balloon expandable stent that would comprise a generally tubular body wherein the stent would be fabricated from titanium and/or tantalum alloy consisting essentially of from 40 to 70 weight percent tantalum, a beta stabilizer selected from the group consisting of vanadium, molybdenum, chromium, iron, and manganese from 2 to 20 weight percent, with the balance being titanium. However, Lau et al. ('158) in view of Lenning et al. ('503) does not specify the diameter of the balloon.

Wiktor ('727) discloses using balloon catheters that have 10 mm and 12 mm diameters to expand a titanium stent (col. 5, lines 58-67 and col. 6, lines 28-52).

Therefore, it would be expected that the size of the expandable balloon of Lau et al. ('158) in view of Lenning et al. ('503) would be the same or similar to the size of the balloon of Wiktor ('727) because Lau et al. ('158) in view of Lenning et al. ('503) and Wiktor ('727) disclose substantially the same system; expanding a titanium alloy;

and the same intended use (use in the human body).

Response to Arguments

Applicant's arguments with respect to claims 1-6, 9-12, and 14-21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessee Roe whose telephone number is (571) 272-5938. The examiner can normally be reached on Monday-Friday 7:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JR

ROY KING
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700